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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,964	02/11/2002	Robyn Lynne Ward	01-1242	4441

20306 7590 06/29/2005

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,964	WARD ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 April 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-167 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-167 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-26 and 75-88, drawn to a nucleic acid sequence encoding a polypeptide of an antibody that binds to a p53 protein.

(Additionally, Applicants must elect a single polynucleotide [SEQ ID Nos 1-30] from those listed in Claim 4 as each SEQ ID NO presents a *distinct* invention not a species.)

Group 2, claim(s) 27-47, drawn to a polypeptide that binds to a p53 protein

(Additionally, Applicants must elect a single amino acid [SEQ ID Nos 31-60] from those listed in Claim 30 as each SEQ ID NO presents a *distinct* invention not a species.)

Group 3, claim(s) 48-54, drawn to a peptide fragment that induces an immune response.

(Additionally, Applicants must elect a single amino acid [SEQ ID Nos 31-60] from those listed in Claim 48 as each SEQ ID NO presents a *distinct* invention not a species.)

Group 4, claim(s) 55-74,108, and 109, drawn to an antibody that binds to a p53 protein.

Group 5, claim(s) 84, 89, 75, and 1 drawn to a non-human vertebrate comprising a host cell.

Group 6, claim(s) 27 and 90-98, drawn to a pharmaceutical composition comprising the polypeptide.

Group 7, claim(s) 1 and 99-101, drawn to a vaccine comprising a nucleic acid sequence.

Group 8, claim(s) 27, 102, and 103, drawn to a method for inducing an immune response comprising administering the polypeptide.

Group 9, claim(s) 27 and 104-107, drawn to a method for treatment or prophylaxis of disease wherein method comprises administering the polypeptide.

Group 10, claim(s) 1 and110-116, drawn to a method for screening for a disease comprising contacting sample from a vertebrate with a nucleic acid probe.

Group 11, claim(s) 55 and 117-118, drawn to a method for screening for a disease comprising contacting a sample from a vertebrate with the antibody.

Group 12, claim(s) 1 and 119-120, drawn to a method of gene therapy.

Group 13, claim(s) 1 and 121-127, drawn to a method for preparing an antibody that binds to p53.

Group 14, claim(s) 1 and 128-131, drawn to a method of locating a nucleic acid sequence encoding a polypeptide of an antibody that binds to p53.

Group 15, claim(s) 48 and 132, drawn to a pharmaceutical composition comprising a peptide fragment.

Group 16, claim(s) 55 and 133, drawn to a pharmaceutical composition comprising an antibody that binds to p53.

Group 17, claim(s) 27 and 134-136, drawn to a pharmaceutical composition comprising a polypeptide.

Group 18, claim(s) 48 and 137-139, drawn to a vaccine comprising a peptide fragment.

Group 19, claim(s) 55 and 140-142, drawn to a vaccine comprising an antibody that binds to p53.

Group 20, claim(s) 48 and 143-144, drawn to a method for inducing an immune response against a disease comprising administering the peptide fragment.

Group 21, claim(s) 48 and 145-148, drawn to a method for the treatment and/or prophylaxis of disease in a vertebrate comprising administering the peptide fragment.

Group 22, claim(s) 55 and 149-150, drawn to a method for inducing an immune response against disease comprising administering the antibody.

Group 23, claim(s) 55 and 151-154, drawn to a method for the treatment and/or prophylaxis of disease in a vertebrate comprising administering a therapeutically effective amount of the antibody.

Group 24, claim(s) 27, 90, and 155-156, drawn to a method for inducing an immune response against disease in a vertebrate comprising administering the pharmaceutical composition comprising the polypeptide.

Group 25, claim(s) 27, 90, and 157-160, drawn to a method for the treatment and/or prophylaxis of disease in a vertebrate comprising administering the pharmaceutical composition comprising the polypeptide.

Group 26, claim(s) 1, 99, 161 and 162, drawn to a method for inducing an immune response against a disease in a vertebrate comprising administering the vaccine comprising a nucleic acid.

Group 27, claim(s) 1, 99, and 163-166, drawn to a method for the treatment and/or prophylaxis of disease in a vertebrate comprising administering the [vaccine] comprising a nucleic acid. (Applicant recites pharmaceutical composition but there is no antecedent basis for a pharmaceutical composition in claim 99).

Group 28, claim(s) 1, 75, and167, drawn to a method of gene therapy.

The inventions listed as Groups 1-25 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking Groups 1-25 appears to be an antibody or antibody fragment that binds to a p53 protein.

However, Caron de Fromentel et al (Oncogene 1999 18:551-557) teach an isolated purified polynucleotide comprising a sequence encoding an antibody and antibody fragment that bind to a p53 protein (Fig. 2). The reference teaches single chain Fv fragments derived from anti-p53 monoclonal antibodies (particularly on p. 552, col.

1). The monoclonal antibodies were obtained from immunizing mice with a mixture of four human p53 mutants (particularly on p. 552, col. 1). The reference teaches said single chain Fv fragments as new molecules for p53-based cancer therapy (p. 556, col. 1), given the known antibody.

Therefore, the technical feature linking the inventions of Groups 1-25 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

Species Election for Group 1

A. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: **DNA** (claim 5) or **RNA** (claim 6).

B. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: residues of the **N-terminus**, **C-terminus**, or the **central domain** of the p53 protein (claims 11, 12, 18).

B(1). Should Applicant elect the N-terminus of a p53 protein, Applicant is further required to elect a species of residues: **about 10 to about 55** (claim 13), **about 10 to 25** (claim 14), **about 40 to about 50** (claim 15), **about 27 to 44** (claim 16), **and about 40 to about 44** (claim 17).

C. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the polynucleotide sequence encodes an immunoglobulin **light chain variable region polypeptide** (claim 19), **heavy chain variable region polypeptide** (claim 19), or the **first polynucleotide sequence encodes an immunoglobulin light chain variable region polypeptide and a second polynucleotide sequence encodes an immunoglobulin heavy chain variable region polypeptide** (claim 20).

D. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The vertebrate species are as follows: **human, non-human primate, murine, bovine, ovine, equine, caprine, leporine, avian, feline,** or **canine** (claim 21 and 22).

E. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 24 and 25).

E(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors**, **tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 26).

E(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 26).

F. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The vector species are as follows: **viral, plasmid, bacteriophage, phagemid, cosmid, bacterial artificial chromosome,** or **yeast artificial chromosome** (claim 76).

G. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The host cell species are as follows: ***E. coli, Bacillus, Strepomyces, Pseudomonas, Salmonella, Serratia,*** **yeast, fungi, plant, insect cells,** or **mammalian cells** (claims 85 and 86).

G(1). Should Applicant elect mammalian cells, Applicant is further required to elect a species of mammalian cell line: **CHO, COS, HeLa, L, murine 3T3, c6 glioma,** or **myeloma cell line** (claim 87).

Species Election for Group 2

H. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: residues of the **N-terminus**, **C-terminus**, or the **central domain** of the p53 protein (claims 33, 34, 40).

H(1). Should Applicant elect the N-terminus of a p53 protein, Applicant is further required to elect a species of residues: **about 10 to about 55** (claim 35), **about 10 to 25** (claim 36), **about 40 to about 50** (claim 37), **about 27 to 44** (claim 38), **and about 40 to about 44** (claim 39).

I. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The homology species are as follows: **45%** (claim 42), **75%** (claim 43), or **95-99%** (claim 44).

J. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 45 and 46).

J(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 47).

J(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 47).

Species Election for Group 3

K. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The fragment species are as follows: comprising between **about 5 and about 50** (claim 49), **about 5 and about 30** (claim 50), or **about 8 and about 20** (claim 51).

Species Election for Group 4

L. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: residues of the **N-terminus**, **C-terminus**, or the **central domain** of the p53 protein (claims 64, 65, 71).

L(1). Should Applicant elect the N-terminus of a p53 protein, Applicant is further required to elect a species of residues: **about 10 to about 55** (claim 66), **about 10 to 25** (claim 67), **about 40 to about 50** (claim 68), **about 27 to 44** (claim 69), **and about 40 to about 44** (claim 70).

M. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 72 and 73).

M(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 74).

M(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 74).

Species Election for Group 6

N. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The polypeptide form species are as follows: **polypeptide/chelate, polypeptide/drug, polypeptide/prodrug, polypeptide/toxin, polypeptide/imaging marker, antibody/chelate, etc.** (claim 91).

N(1). Should Applicant elect polypeptide/toxin or antibody/toxin, Applicant is further required to elect a species of toxin: **ricin, abrin, *Diptheria* toxin or *Pseudomonas* endotoxin (PE 40)** (claim 96).

N(2). Should Applicant elect a polypeptide/imaging marker or antibody/imaging marker, Applicant is further required to elect a species of imaging marker: **gadolinium, ^{125}I, ^{131}I, ^{123}I, ^{111}In, ^{105}Rh, etc.** (claims 97 and 98).

Species Election for Group 9

O. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 105 and 106).

O(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 107).

O(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 107).

Species Election for Group 21

P. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 146 and 147).

P(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 148).

P(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 148).

Species Election for Group 23

Q. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 152 and 153).

Q(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 154).

Q(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 154).

Species Election for Group 25

R. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 158 and 159).

R(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 160).

R(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 160).

Species Election for Group 27

S. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The disease species are as follows: **cancer, rheumatoid arthritis,** or **coronary heart disease** (claims 164 and 165).

S(1). Should Applicant elect cancer, Applicant is further required to elect a species of cancer: **carcinogenic tumors, tumors of epithelial origin, mesenchymal tumors,** or **haemopoietic tumors** (claim 166).

S(2). Should Applicant elect tumors of epithelial origin, Applicant is further required to elect a species of tumor: **colo-rectal cancer, breast cancer, lung cancer, head and neck tumors, hepatic cancer, etc.** (claim 166).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species has a different special technical feature which encompasses distinct method steps, objectives, and reagents all of which impart different biological functions and uses.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER